

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k033851

B. Analyte:

Urinary Glucose, Urinary Ketones

C. Type of Test:

Qualitative and semi-quantitative

D. Applicant:

Hypoguard USA, Inc.

E. Proprietary and Established Names:

DiaScreen[®] Reagent Strips for Urinalysis

F. Regulatory Information:

1. Regulation section:
21 CFR § 862.1340; 21 CFR § 862.1435
2. Classification:
Class II, Class I
3. Product Code:
JIL; JIN
4. Panel:
75 Clinical Chemistry

G. Intended Use:

1. Intended Use
DiaScreen[®] Reagent Strips for Urinalysis are intended for the qualitative and semi-quantitative measurement of glucose and ketones in urine. They are intended for both professional and over-the-counter use.

2. Indication(s) for use:
DiaScreen[®] Reagent Strips for Urinalysis are intended for the qualitative and semi-quantitative measurement of glucosuria (glucose in urine). These measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia.

DiaScreen[®] Reagent Strips for Urinalysis are intended for the qualitative and semi-quantitative measurement of ketones in urine. Identification of ketones is used in the diagnosis and treatment of acidosis or ketosis and for monitoring patients on ketogenic diets and patients with diabetes.

3. Special condition for use statement(s):
This submission is for an over-the-counter version of the previously cleared professional use device for glucose and ketones. Consumers can perform the test using the midstream technique or the dip and read technique.

4. Special instrument Requirements:

N/A

H. Device Description:

The DiaScreen[®] Reagent Strips for Urinalysis consist of a plastic strip coated with one or more dry reagents, each specific for a particular analyte. This submission included three configurations: one to detect glucose, one to detect ketones, and one to detect both. When saturated with urine, the dry reagents change color in a chemical reaction with their associated analyte. The reagent blocks are read visually against a color chart.

I. Substantial Equivalence Information:

1. Predicate device name(s):
DIA SCREEN[®] 10 Way Reagent Strips for Urinalysis
2. Predicate K number(s):
K961375
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analytes	Glucose and/or Ketones	Glucose and/or Ketones plus up to eight other analytes
Methodology	Same	Dry Reagents with Visual Color Change
Measurement Range	Same	Ketones: Neg, Trace, 15, 40, 80, 160 Glucose: Neg, 50, 100, 250, 500, 1000
Sample Size	Same	Sufficient Volume to Cover Reagent Blocks When Dipped
Read Time	Same	60 seconds
Differences		
Item	Device	Predicate
Intended Use	Professional and Over the Counter Use	Professional Use Only
Sample Application	Dip and Read OR Midstream	Dip and Read

J. Standard/Guidance Document Referenced (if applicable):

None referenced

K. Test Principle:

The glucose test is based on a sequential enzyme reaction. First, glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from blue-green to brown.

The ketone test is based on a reaction between acetoacetic acid in the urine with nitroprusside in the dry reagent. The color of the reagent pad ranges from tan for no reaction (negative result) through pink and purple for a positive result. The sponsor states that acetone and beta-hydroxybutyric acid make no significant contribution to the reaction.

L. Performance Characteristics (if/when applicable):

1. Analytical performance: The previous submission (K961375) included dry reagents for up to ten analytes and was intended for professional use only. Performance data for glucose and ketones for that submission are briefly summarized here.

a. Precision/Reproducibility:

The data demonstrated adequate reproducibility between masked operators and between different strip lots.

b. Linearity/assay reportable range:

The data demonstrated a linear relationship between spiked-in values and the semi-quantitative readings for glucose and ketones.

c. Traceability (controls, calibrators, or method):

N/A

d. Detection limit:

Sensitivity was demonstrated to the lowest reporting block

e. Analytical specificity:

For ketones, L-Dopa and 2-Mercaptoethane at 15 mg/dL were observed to cause a positive bias. For glucose, ascorbic acid at 50 mg/dL and acetoacetic acid at 40 mg/dL were observed to cause a false negative result. It was also observed that a high specific gravity could cause a negative bias for glucose.

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

In the previous submission (K961375) two lots of the device were compared with the predicate. For glucose and ketones, 100% of the readings were within 1 color block of the predicate.

In this submission, the sponsor demonstrated that untrained consumers, after reading the proposed package insert, could use the test correctly and achieve results comparable to trained professional users. A discrepant result was defined as a consumer reading more

than one color block away from the professional reading. The overall agreement for both ketones and glucose was 341 out of 346 or 98.6% agreement.

The study consisted of two parts. The first part of the study compared glucose and ketone results between consumers and professionals on synthetic urine using the dip and read method. Samples were tested for both glucose and ketones and were a mixture of positives and negatives.

Results were as follows for n = 104

Analyte	Same Color Block	Within +/- One Color Block
Glucose	77%	98%
Ketones	69%	97%

When broken down by concentration, the following was observed (discrepant results in large bold type):

n = 104

Glucose mg/dL - Professional	1000	1					7
	500				2	7	
	250			1	11	1	
	100			6	4		
	50	2	6				
	Neg	43	12		1		
		Neg	50	100	250	500	1000

Glucose mg/dL – Consumers

n = 104

Ketones mg/dL - Professional	160				2	5	6
	80				5	2	2
	40		1	4	2		
	15		4	8			
	5	12	2				
	Neg	49					
		Neg	5	15	40	80	160

Ketones mg/dL – Consumers

There were five discrepant results using the dip and read method reported by four participants (one participant had a discrepant result for both glucose and ketones).

The second part of the study compared glucose and ketone results between consumers and professionals using the midstream method. Because this part of the study used unaltered clinical samples and because of the difficulty in obtaining positive samples, some of the samples (Site 1, n = 42) were employees of the sponsored who had been prescreened and were known to be positive. The remaining samples (Site 2, n = 27) were not prescreened and were obtained from the general public. Consumers conducted their own midstream test and collected a urine sample in a specimen cup for professional testing by the dip and read method immediately afterward.

Overall results were as follows:

	Site 1 (n = 42)		Site 2 (n = 27)	
Analyte	Same Color Block	Within +/- One Color Block	Same Color Block	Within +/- One Color Block
Glucose	100%	100%	100%	100%
Ketones	95%	100%	93%	100%

When broken down by concentration, the following was observed:

Site 1 (n = 42)

Glucose mg/dL - Professional	1000						3
	500					4	
	250				3		
	100			1			
	50						
	Neg	31					
		Neg	50	100	250	500	1000

Glucose mg/dL – Consumers

Site 2 (n = 27)

Glucose mg/dL - Professional	1000						2
	500						
	250						
	100						
	50						
	Neg	25					
		Neg	50	100	250	500	1000

Glucose mg/dL - Consumers

Site 1 (n = 42)

Ketones mg/dL - Professional	160						
	80						
	40				2		
	15		1	1			

	5	1	5				
	Neg	32					
		Neg	5	15	40	80	160

Ketones mg/dL – Consumers

Site 2 (n = 27)

Ketones mg/dL - Professional	160						
	80						
	40			1	2		
	15						
	5	1					
	Neg	23					
		Neg	5	15	40	80	160

Ketones mg/dL - Consumers

There were no discrepant results using the midstream method.

The sponsor also required a Test Interpretation Exit Questionnaire to assess the participants' ability to understand the information presented in the labeling. Questions were asked concerning the relationship between blood and urine glucose levels, the presence of glucose or ketones in the urine and how it relates to diet, and the significance of large amounts of ketones and/or glucose in the urine. Overall, greater than 96% of participants answered all questions correctly. The question regarding the significance of large amounts of ketones and/or glucose in the urine was answered correctly by 100% of the participants.

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical sensitivity:

N/A

b. Clinical specificity:

N/A

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

N/A

M. Conclusion:

Based upon the information provided for the file, I recommend that the over-the-counter version of the DiaScreen[®] Reagent Strips for Urinalysis be found substantially equivalent to the predicate device.